KURARAY MEDICAL INC.
Dental Material Department
12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
Phone : +81-6-348-2603
Facsimile: +81-6-348-2552

K012737

SEP 1 4 2001

510(k) SUMMARY

1. Submitter

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) Contact person	Koji Nishida DENTAL MATERIAL DEPARTMENT
4) Date	August 9, 2001
5) Contact person in U.S.A.	Masaya Sasaki 30th Fl. Metlife Building, 200 Park Avenue, New York, NY 10166 Telephone : (212)-986-2230 1-(800)-879-1676 Facsimile : (212)-867-3543

2. Name of Device

1) Proprietary Name	CHROMA ZONE COLOR STAIN
2) Classification Name	Tooth shade resin material (21CFR 872.3690)
3) Common/Usual Name	Resin-based stain material

3. Predicate device:

Kuraray Co., Ltd. will transfer the medical device business and the relevant functions including manufacturing facilities to its subsidiary company named Kuraray Medical Inc. on October 1st 2001. The aim of 510(k) submission is to alter the name and address of manufacturer, and not to intend other changes.

The predicate device is as follow.

1. CHROMA ZONE COLOR STAIN by Kuraray Co., Ltd. (K982259)

4. Description for the premarket notification

CHROMA ZONE COLOR STAIN is classified into tooth shade resin material, CFR 21 Section 872.3690, because it is a device composed of materials such as dimethacrylate monomers and inorganic fillers intended to be used for laboratory fabrication of jacket crown, facing crown, inlay and onlay restorations.

5. Statement of the intended use

The intended uses of this device are as follows. They are completely the same as CHROMA ZONE COLOR STAIN manufactured by Kuraray Co., Ltd. (K982259).

This product is designed to be used for developing color characterization for resin-based:

1) Facing crown
2) Jacket crown
3) Inlay and Onlay

6. Statement of the technological characteristics and safety

This device is essentially the same as CHROMA ZONE COLOR STAIN manufactured by Kuraray Co., Ltd. (K982259). Therefore the technological characteristics, chemical ingredients and safety of this device are completely the same as CHROMA ZONE COLOR STAIN.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2001

Kuraray Medical Incorporated
C/O Ms. Masaya Sasaki
Kuraray America, Incorporated
30th Floor Metlife Building
200 Park Avenue
New York, New York 10166

Re: K012737
Trade/Device Name: Chroma Zone Color Stain
Regulation Number: 872.3690
Regulation Name: Resin-Based Stain Material
Regulatory Class: II
Product Code: EBF
Dated: August 9, 2001
Received: August 14, 2001

Dear Ms. Sasaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012737
Device Name: CHROMA ZONE COLOR STAIN

K012737

Indications for Use

CHROMA ZONE COLOR STAIN is designed to be used for developing color characterization for resin-based:

1) Facing crown
2) Jacket crown
3) Inlay and Onlay

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012737